Remarks

Claims 1, 5-9, 11, 12, 14, 16-31, 57-62, and 65-70 are pending after entry of this Amendment. In this Amendment, claims 21 and 57-61 have been amended, and new claims 65-70 have been added. No new matter has been introduced. The specification supports all amendments and new claims.

Claim Rejections

The numbered paragraphs below correspond to the Examiner's numbered paragraphs in the Final Office Action of November 29, 2006.

1. Applicants acknowledge the withdrawal of claims 6, 7, 11, 12, 14, 17, 20, and 58. First, Applicants believe that the newly added claims are within the bounds of the elected species. Upon allowance of the generic independent claims, Applicants reserve the right to add new dependent claims directed to the non-elected species. Second, since generic claim 1 is now believed to be in condition for allowance, ***Applicants respectfully request rejoinder of the withdrawn non-elected species***.

3. Claim 4 was objected to under 37 CFR 1.75(c) for failing to further limit the subject matter of a previous claim. Claim 4 has been canceled, which makes this objection moot.

4. Claim 15 was objected to because the Office deemed a phrase in the claim to be repetitive. Cancellation of claim 15 renders this objection moot.

5/6. Claims 15, 21-31, 47-56, and 64 were rejected under 35 U.S.C. 112, first paragraph, for containing subject matter which was not described in the specification. The rejection of claims 15 and 47-56 (which depend from claim 15) is moot as these claims have been canceled.

Claim 21 recites "deflating the balloon in preparation for the intended use of the balloon." The Examiner states there is no support for the limitation of deflating the balloon "in preparation for the intended use of the balloon." However, this limitation is supported by the originally-filed application, which provides that the balloon can be deflated prior to or during the process of removal of fluid (see original claim 10, and Application page 9, lines 3-19). Deflating of the balloon prior to or during the process of removal of fluid occurs before the intended use of the balloon. As such, deflating the balloon prior to or during the process of removal of fluid results in and, thereby supports, deflating the balloon prior the intended use of the balloon.

Claims 22-31, which depend from claim 21, are supported by the specification as originally filed for the reasons given above for claim 21.

Regarding claim 64, the Examiner states that there is no support for the limitation of deflating the balloon "after removal of at least some of the fluid." However, this limitation is supported by the originally-filed specification, which provides that a balloon can be deflated during the removal of fluid performed through drying (see Application page 9, lines 3-19).

Drying is a process that can occur over a period of time. Thus, deflating the balloon during a drying process, such as in the middle of a drying time period, provides clear support for deflating the balloon after ***at least some*** of the fluid has been removed from or dried off the balloon.

7/8. Claims 10, 13, 39, and 40 were rejected under 35 U.S.C. 102(e) as being anticipated by Kokish (6,544,223). This rejection is rendered moot by cancellation of claims 10, 13, 39, and 40.

9. Claims 13, 15, 21, 24-26, 28-29, 31, 43-44, 46, 50-52, 54, 56, and 63 were rejected under 35 U.S.C. 102(b) as being anticipated by Barry et al. (US 2002/0037358).

The rejection of claims 13, 15, 43, 44, 46, 50-52, 54, 56, and 63 are moot as these claims have been canceled.

Independent claim 21 has been amended to also recite "applying a substance to an outer surface of a wall membrane of the balloon" and further recites "deflating the balloon … such that the substance is contained ***within the wall membrane of the balloon.***" Barry et al. fails to teach these limitations. Barry et al. simply teaches a drug impregnated into the polymer coating that is applied to the balloon. That is, ***the drug is within the polymer coating that has been applied to the balloon and is not within the wall membrane of the balloon itself***. Even if the Examiner interprets the polymer coating in Barry et al. as being part of the wall membrane, Barry et al. fails to teach ***deflating*** the balloon with the polymer coating such that the drug is contained within the polymer coating.

Claim 24 includes the limitation that the inflated state of the balloon "is maintained at the same or generally the same level during the application of the substance to the balloon." This limitation is neither directly taught by nor inherently present in Barry et al. The Examiner incorrectly argues that, because Barry et al. does not teach inflating or deflating the balloon during the deposition step, "the inflated state of the balloon ***must*** be maintained at the same or generally the same level during the deposition step" (Final Office Action, p. 5) (Applicants' emphasis). For anticipation under 35 U.S.C. §102, "[a]ny feature not directly taught must be inherently present" in the cited reference (MPEP 706.02, IV) (Applicants' emphasis). Further, "[t]he fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish inherency of that result or characteristic" (MPEP 2112, IV, citing In re Rijckaert, 9 F.3d 1531, 1534 (Fed. Cir. 1993)) (see also In re Robertson, 169 F.3d 743, 745 (Fed. Cir. 1999). ***Barry et al. does not prohibit inflating or deflating the balloon during the deposition step. As such, Barry et al. allows for inflating or deflating of the balloon during the deposition step, in which case the inflated state of the balloon during the deposition step in Barry et al. is not maintained at the same or generally the same level. Therefore, it does not follow that the inflated state of the balloon must be maintained at the same or generally the same level during the deposition step in Barry et al. That is, the limitation that the inflated state of the balloon "is maintained at the same or generally the same level during the application of the substance to the balloon" is not inherently present in Barry et al.***

Claims 25 and 26 recite "removing at least some of the fluid carrier to deposit the substance ***within the wall membrane of the balloon***." Barry et al. fails to teach this limitation as explained above in connection with claim 21.

Claim 29 recites that "the wall membrane of the balloon is made from a porous material." Examiner argues that because Applicants teach polyurethane as one of the preferred porous materials, "the polyurethane membrane of Barry must necessarily be a porous material" (Final Office Action, p. 5). Applicants traverse this rejection as ***Barry et al. simply teaches that polyurethane may be in a polymer coating on a balloon, not the wall membrane of the balloon itself***. Further, ***there is no teaching in Barry et al. that the polyurethane it mentions must necessarily be porous***. Applicants direct the Examiner's attention to US 4,367,327 to Holker et al., which is directed to a non-porous polyurethane film and, thus, indicates that polyurethanes are not necessarily porous.

10. Claims 13, 21, 24, 28-29, 31, 41, 46, 57, and 59-60 were rejected under 35 U.S.C. 102(b) as being anticipated by Reiss et al. '963 (US 2003/0032963).

The rejection of claims 13, 41, and 46 is moot as these claims have been canceled.

Regarding independent claim 21, Reiss et al. '963 fails to teach the limitation of deflating the balloon "such that the substance is contained ***within the wall membrane of the balloon.***" Although Reiss et al. '963 teaches coating a balloon with a substance, it fails to teach that the substance is contained ***within*** a wall membrane of the balloon.

Claim 24 recites that the inflated state of the balloon "is maintained at the same or generally the same level during the application of the substance to the balloon. The Examiner argues that because Reiss et al. '963 does not teach that the inflated state of the balloon is changed during the coating process, the inflated state of the balloon must necessarily be

maintained at the same or generally the same level during the coating step. Applicants traverse this rejection for the reasons given above in paragraph 9 in connection with claim 24.

Claim 57 has been amended to include the limitation of "collapsing the pores after applying the substance in the fluid carrier to the balloon." Reiss et al. '963 fails to teach this limitation.

11. Claims 13, 21, 24, 28, 31, 46, and 64 were rejected under 35 U.S.C. 102(b) as being anticipated by Sahatjian et al. (US 5,674,192).

The rejection of claims 13, 46, and 64 is rendered moot by cancellation of these claims.

Regarding independent claim 21, Sahatjian et al. fails to teach the limitation of deflating the balloon "such that the substance is contained ***within the wall membrane of the balloon.***" The Examiner simply states that the in Sahatjian et al. the balloon is inflated, coated with a drug, dried, and then deflated. However, Sahatjian fails to disclose that a drug is contained ***within*** the wall membrane of the balloon for the reasons stated above in paragraph 9 in connection with claim 21.

Claim 24 recites that the inflated state of the balloon "is maintained at the same or generally the same level during the application of the substance to the balloon. The Examiner argues that because Sahatjian et al. does not teach that the inflated state of the balloon is changed during the coating process, the inflated state of the balloon must necessarily be maintained at the same or generally the same level during the coating step. Applicants respectfully disagree and request that this rejection be withdrawn for the reasons given above in paragraph 9 in connection with claim 24.

12/13/14. Claims 1, 4-5, 8-10, 15, 19, 22, 32-35, 39-40, 42, 47-50, 54, 56, 58-59, 61-62, and 64 were rejected under 35 U.S.C. 103(a) as being unpatentable over Reiss et al. '963 (US 2003/0032963).

Claim 1 recites inflating a balloon to an inflated state that "is greater than a range of intended expanded configuration of the balloon." The Examiner acknowledges that Reiss et al. '963 does not explicitly teach this limitation, but argues that it would have been obvious to have inflated the balloon "to an inflated state greater than a range of an intended expanded configuration as opposed to the wholly inflated state of Reiss … because the state of inflations are ***so close***." (Applicants' emphasis). However, Reiss et al. '963 merely states that "the balloon can be wholly or partially inflated … before the coating is performed" (para. 201). ***Reiss et al. '963 fails to teach or suggest any sort of close relationship between "wholly or partially inflated … before the coating is performed," in one hand, and an inflated state that is greater than a range of intended expanded configuration, in the other hand.*** Further, the present Application provides that:

> Intended expanded configuration is defined as inflation of a balloon to a diameter or size within the range of its intended use or design. The intended expanded configuration is provided by the manufacturer of the balloon (or can be determined by one having ordinary skill in the art) and is intended to include the range of diameter of use or the range of pressure to be applied for the planned performance of the balloon. (Application as originally filed, p. 7, lines 17-19)

Nowhere is it stated in the Application that the term "greater than an intended range of expansion" is close to "wholly or partially" inflated.

In rejecting claim 1, the Examiner also states that "[a] *prima facie* case of obviousness exists where the claimed ranges and prior art do not overlap but are ***close enough*** that one [of]

ordinary skill in the art would have expected them to have the same properties" (Applicants' emphasis) and cites *Titanium Metals v. Banner* (227 USPQ 773) and MPEP 2144.05. Applicants respectfully submit that this statement and the accompanying citations do not apply to claim 1 as they apply only to claims that expressly recite numerical ranges or limitations. Even if the Examiner maintains that they apply to claim 1, Reiss et al. '963 fails to teach or suggest any sort of close relationship between "wholly or partially inflated ... before the coating is performed," in one hand, and an inflated state that is greater than a range of intended expanded configuration, in the other hand, as previously explained.

Cancellation of claims 4, 10, 15, 32-35, 42, 47-50, 54, 56, and 64 renders rejection of these claims moot.

Regarding claim 22, Reiss et al. '963 fails to teach or suggest the limitation of inflating a balloon to an inflated state that is a "hyper-inflated state." The Application provides that:

> hyperinflation is defined as any diameter ***above intended expanded configuration*** but less than a diameter or size in which the balloon will be damaged or no longer suitable for its intended use (page 7, line 22 to page 8, line 1)

Reiss et al. '963 fails to teach or suggest the limitation inflating a balloon to a hyper-inflated state (i.e., to an inflated state above its intended expanded configuration) for the reasons given above in connection with claim 1.

Regarding claim 58, Reiss et al. '963 fails to teach or suggest the limitation of modifying a balloon from a hyper-inflated state (i.e., from an inflated state above its intended expanded configuration) for the reasons given above in connection with claim 1.

15. Claims 16 and 18 were rejected under 35 U.S.C. 103(a) as being unpatentable over Reiss et al. '963 in view of Fukaya (US 6,613,066). Applicants submit that claims 16 and 18, which depend directly or indirectly from claim 1, are patentable over Reiss et al. '963 in view of Fukaya, as none of these references alone or in combination teach or suggest inflating a balloon to an inflated state that is "greater than a range of an intended expanded configuration of the balloon" as recited in claim 1.

16. Claims 27, 45, and 53 were rejected under 35 U.S.C. 103(a) as being unpatentable over Barry et al. in view of Reiss '617 (US 6,913,617).

Regarding claim 27, none of these references alone or in combination teach or suggest the limitation of "removing at least some of the fluid carrier to deposit the substance ***within the wall membrane of the balloon***." Barry et al. simply teaches a drug coating impregnated into the polymer coating of the balloon, but not ***within*** the wall membrane of the balloon. Reiss '617 teaches substances that are impregnated in, located on, or provided underneath the polymeric coating of a stent (col. 2, lines 2-5), but not within the wall membrane of a balloon.

17. Claims 25-27, 36-38, 43-45, and 51-53 were rejected under 35 U.S.C. 103(a) as being unpatentable over Reiss et al. '963 in view of Reiss '617.

Claims 25-27 recite the limitation of "removing at least some of the fluid carrier to deposit the substance ***within the wall membrane of the balloon.***" None of these references alone or in combination teach or suggest this limitation for the reasons given above in paragraph 10 in connection with claim 21 and in paragraph 16 in connection with claim 27.

Rejection of claims 43-45 and 51-53 are moot as these claims have been canceled.

18. Claims 30 and 55 were rejected under 35 U.S.C. 103(a) as being unpatentable over Barry et al. in view of Boulais (US 2004/0213893).

Claim 30 includes the limitation that a wall membrane of a balloon that comprises an "inner non-porous layer and an outer porous layer." None of these references alone or in combination teach or suggest this limitation. As previously mentioned, Barry et al. simply teaches a polymer coating on a balloon where the polymer coating, not the wall membrane of the balloon, may include polyurethane (a material that can be porous). The Examiner incorrectly states that "Boulais teaches that a balloon catheter can be coated with multiple layers of different polymer materials, such as polyurethanes and polylactic acid (i.e., a non-porous material)" (Final Office Action, p. 10). Boulais is directed to coating a stent, not a balloon, and teaches using a balloon to mask the inner surface of the stent when the stent is being coated with a polymer such as polylactic acid (see Abstract and para. 9). There is no disclosure or suggestion whatsoever in Boulais of a wall membrane of a balloon being formed of polyurethane and polylactic acid or that the wall membrane has an inner non-porous layer and an outer porous layer.

New Claims

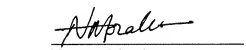
Applicants submit that Kokish, Barry et al., Reiss et al. '963, Sahatjian et al., Fukaya et al., Reiss '617, and Boulais, alone or in combination, fail to teach or suggest the claimed limitations of new claims 65-70. In particular, none of these references teach or suggest the limitation of "collapsing pores" of a balloon after applying a substance to the balloon. Also,

none of these references teach or suggest the limitation of "inhibiting" evaporation or removal of the fluid carrier.

Summary

Removal of the rejections and allowance of the application is hereby respectfully solicited. If the Examiner has any questions or concerns, the Examiner is invited to telephone the undersigned attorney at (415) 393-9857.

Respectfully submitted,



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